NOV 2 2 2006

510(k) SUMMARY

Panalok RC Quickanchor Plus w/ Orthocord
Panalok RC Quickanchor Plus Dual w/ Orthocord
Panalok Anchor w/ Orthocord

Submitter's Name and Address:

DePuy Mitek
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Contact Person

Kristine Christo
Senior Regulatory Affairs Specialist
DePuy Mitek
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Telephone: 508-828-3359
Facsimile: 508-977-6911
e-mail: KChristo@Dpyus.jnj.com

Name of Medical Device

Classification Name: Screw, Fixation, Bone Staple
Fastener, Fixation, Biodegradable, Soft Tissue

Common/Usual Name: Appliance for reconstruction of soft tissue to bone

Proprietary Name: Panalok Quickanchor Plus
Panalok RC QuickAnchor Plus Dual Suture
Panalok Anchor

Substantial Equivalence

Panalok RC Quickanchor Plus (with ORTHOCORD) and Panalok RC Quickanchor Plus Dual Suture (with ORTHOCORD) are substantially equivalent to:
Panalok RC Quickanchor Plus, K041117 , manufactured by DePuy Mitek.

Panalok Anchor (with ORTHOCORD) is substantially equivalent to:
Panalok Anchor, K970896 , manufactured by DePuy Mitek.

Device Classification

Bone anchors/screws are classified by the FDA as Class II Medical Devices under the generic category of Single/Multiple component

	metallic bone fixation appliances and accessories. Panalok RC Quickanchor Plus carry FDA product code JDR, and is classified as a fixation screw/bone staple under 21 CFR 888.3030. Panalok Anchor carry FDA product code MAI, and is classified as a Fastener, fixation biodegradable, soft tissue under 21 CFR 888.3030
Device Description	Panalok RC Anchor Plus (with ORTHOCORD), Panalok RC Anchor Plus Dual Suture (with ORTHOCORD) and Panalok are preloaded, PLA disposable suture anchor/ inserter assemblies designed to allow soft tissue repair to bone. The anchors are an identical anchors as that of the Panalok RC Anchor Plus (K041117) and Panalok Anchor (K970896) in design, configuration and dimensions. The anchor system may be sold with Ethibond Suture, Panacryl Suture, Orthocord Suture.
Indications for Use	The Mitek Panalok RC QuickAnchor Plus with Orthocord and Mitek Panalok RC QuickAnchor Plus Dual Suture with Orthocord are intended for fixation of USP size #2 suture to bone for the indications listed below. Shoulder: rotator cuff repair The Mitek Panalok Anchor with Orthocord are indicated for use in soft tissue to bone fixation in association with adequate post- operative immobilization as follows:. Open Procedure Shoulder: Bankart repair, SLAP lesion repair, rotator cuff repair, capsule shift/ capsulo-labral reconstruction at anterior glenoid rim site, shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus, , biceps tenodesis, acromio-clavicular separation . Elbow: Biceps tendon reattachment Ankle: Achilles tendon repair/reconstruction, lateral stabilization, medial stabilization at the medial talus site Knee: Medial collateral ligament repair, lateral collateral ligament repair, joint capsule closure to anterior proximal tibia, posterior oblique ligament or joint capsule to tibia repair, extra capsular reconstruction / ITB tenodesis, patellar ligament and tendon avulsion repairs Arthroscopic Procedures shoulder: Bankart repair, SLAP lesion repair, rotator cuff repair, , capsule shift repair (glenoid rim)

Safety and Performance	The determination of substantial equivalence for these devices were based on a detailed device descriptions, and conformance to consensus and voluntary standards. Bench testing was performed demonstrating that the ORTHOCORD suture conformed to the USP monograph for absorbable sutures, and the suture compatibility and deployment met predetermined acceptance criteria. Based on the indications for use, technological characteristics, and comparison to predicate devices, the Panalok RC Quickanchor Plus (with ORTHOCORD), Panalok RC Quickanchor Plus Dual Suture (with ORTHOCORD) and Panalok Anchor (with ORTHOCORD) have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Mitek, a Johnson & Johnson Company
% Ms. Kristine Christo
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

NOV 2 2 2006

Re: K063273
Trade/Device Name: Panalok RC QuickAnchor Plus with Orthocord, Panalok RC QuickAnchor Plus Dual Suture with Orthocord, and Panalok Anchor with Orthocord
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR, MAI
Dated: October 27, 2006
Received: October 30, 2006

Dear Ms. Christo:

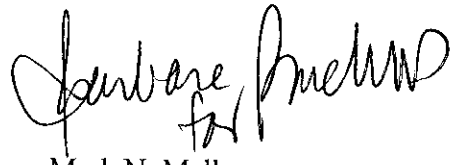
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K063273

Device Names: Panalok RC Quickanchor Plus, with Orthocord
Panalok RC Quickanchor Plus Dual Suture with Orthocord

Indications for Use:

The Mitek Panalok RC QuickAnchor Plus with Orthocord and Mitek Panalok RC QuickAnchor Plus Dual Suture with Orthocord are intended for fixation of USP size #2 suture to bone for the indications listed below.

Shoulder: rotator cuff repair

Prescription Use ____√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K063273

Page 1 of ____

INDICATIONS FOR USE

510(k) Number (if known): K063273

Device Names: Panalok Anchor with Orthocord

Indications for Use:

The Mitek Panalok Anchor with Orthocord are indicated for use in soft tissue to bone fixation in association with adequate post- operative immobilization as follows:.

Open Procedure Shoulder: Bankart repair, SLAP lesion repair, rotator cuff repair, capsule shift/ capsulo-labral reconstruction at anterior glenoid rim site, shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus, , biceps tenodesis, acromio-clavicular separation .

Elbow: Biceps tendon reattachment

Ankle: Achilles tendon repair/reconstruction, lateral stabilization, medial stabilization at the medial talus site

Knee: Medial collateral ligament repair, lateral collateral ligament repair, joint capsule closure to anterior proximal tibia, posterior oblique ligament or joint capsule to tibia repair, extra capsular reconstruction / ITB tenodesis, patellar ligament and tendon avulsion repairs

Arthroscopic Procedures shoulder: Bankart repair, SLAP lesion repair, rotator cuff repair, , capsule shift repair (glenoid rim)

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)